RVD2009-08

Re-evaluation Decision

# Hexazinone

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# Overview

## Re-evaluation Decision

After a re-evaluation of the herbicide hexazinone, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting continued registration of products containing hexazinone for sale and use in Canada.

An evaluation of available scientific information found that products containing hexazinone do not present unacceptable risks to human health or the environment when used according to the revised label directions. As a condition of the continued registration of hexazinone uses, new risk-reduction measures must be included on the labels of all products, and additional data are being requested by the PMRA.

The regulatory approach for the re-evaluation of hexazinone was first presented in Proposed Re-evaluation Decision PRVD2007-13, *Hexazinone*, a consultation document.[1] This Re-evaluation Decision[2] describes this stage of PMRA's regulatory process for the re-evaluation of hexazinone as well as summarizes the Agency's decision and the reasons for it. Appendix I summarizes the comments received during the consultation process and provides the PMRA's response to these comments. This decision is consistent with the proposed re-evaluation decision stated in PRVD2007-13. To enable registrants to comply with this decision, the PMRA will inform the registrants of products containing hexazinone of the specific requirements affecting their product registrations as well as of the regulatory options available to them.

## What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers the potential risks as well as value of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Hexazinone, one of the active ingredients in the current re-evaluation cycle, has been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian regulatory decisions;
- it addresses the active ingredient and the main formulation types registered in Canada;

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

and

- it is relevant to registered Canadian uses.

Based on the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA has made a regulatory decision and requires appropriate risk-reduction measures for Canadian uses of hexazinone. In this decision, the PMRA took into account the Canadian use pattern and issues (e.g. the federal Toxic Substances Management Policy).

The USEPA re-evaluated hexazinone and published its conclusions in a 1994 RED and the 2002 Tolerance Reassessment Eligibility Document (TRED) for hexazinone.

For more details on the information presented in this Re-evaluation Decision, please refer to the Science Evaluation in the related Proposed Re-evaluation Decision PRVD2007-13, *Hexazinone*.

## What Is Hexazinone?

Hexazinone is a non-selective herbicide used to control broadleaf weeds and woody plant species in cropland and non-cropland areas, and as a selective herbicide in woodland management practices. It is registered for use on alfalfa, blueberries, Christmas tree plantations and woodland management areas as well as in non-cropland areas such as railroad, highways, utility and pipeline rights-of-way, petroleum tank farms, storage areas, industrial plant sites and other similar areas. Hexazinone is applied using ground or aerial equipment. Aerial applications are solely for site preparation in woodland management areas. Applications are made by farm workers and professional applicators.

## Health Considerations

### Can Approved Uses of Hexazinone Affect Human Health?

**Hexazinone is unlikely to affect your health when used according to the revised label directions.**

People could be exposed to hexazinone by consuming food and water, working as a mixer/loader/applicator or entering treated sites. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that hexazinone was unlikely to affect human health provided that risk-reduction measures were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required.

### Maximum Residue Limits

The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in or on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Hexazinone is currently registered in Canada for use on alfalfa and blueberries and could be used in other countries on crops that are imported into Canada. No specific MRLs have been established for hexazinone in Canada. Where no specific MRL has been established, a default MRL of 0.1 ppm applies, which means that pesticide residues in a food commodity must not exceed 0.1 ppm. However, changes to this general MRL may be implemented in the future as indicated in Discussion Document DIS2006-01, *Revocation of 0.1 ppm as a General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*. If and when the general MRL is revoked, a transition strategy will be established to allow permanent MRLs to be set.

## Environmental Considerations

### What Happens When Hexazinone Is Introduced Into the Environment?

**Hexazinone is unlikely to affect non-target organisms when used according to the revised label directions.**

Non-target organisms such as birds, mammals, insects, aquatic organisms and terrestrial plants could be exposed to hexazinone in the environment. Environmental risk is assessed by the risk quotient method—the ratio of the estimated environmental concentration to the relevant effects endpoint of concern. The resulting risk quotients are compared to corresponding levels of concern. A risk quotient less than the level of concern is considered a low risk to non-target organisms, whereas a risk quotient greater than the level of concern indicates some degree of risk.

The USEPA concluded that the reregistration of hexazinone was acceptable provided risk-reduction measures to further protect the environment were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required.

## Measures to Minimize Risk

The labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of hexazinone, the PMRA is requiring further risk-reduction measures for product labels.

**Human Health**

- Additional protective equipment to protect mixers/loaders/applicators
- A restricted-entry interval to protect workers re-entering treated sites

**Environment**

- Additional advisory label statements to reduce potential runoff to surface water and leaching to groundwater
- Buffer zones to protect non-target, sensitive aquatic and terrestrial habitats

Appendix II lists all the required label amendments.

## What Additional Scientific Information Is Required?

The following data are required as a condition of continued registration under section 12 of the *Pest Control Products Act*. The registrants of this active ingredient are required to provide these data or an acceptable scientific rationale within the timeline specified in the decision letter.

- Data to confirm that acceptable levels of hexazinone and its metabolites in groundwater and surface water are not exceeded

- Any existing Canadian water monitoring data (including the groundwater quality monitoring study being undertaken in New Brunswick[3])

- Terrestrial vascular plants toxicity studies—seedling emergence and vegetative vigour

## Other Information

Any person may file a notice of objection[4] regarding this decision on hexazinone within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Health Canada website, Request a Reconsideration of Decision, or contact the PMRA's Pest Management Information Service.

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3 Agriculture and Agri-Food Canada, http://www.agr.gc.ca, Pesticides.

4 As per subsection 35(1) of the *Pest Control Products Act*.

## List of Abbreviations

| | |
|---|---|
| a.i. | active ingredient |
| AGDISP | AGricultural DISPersal |
| ASAE | American Society of Agricultural Engineers |
| DWLOC | drinking water level of comparison |
| $EC_{50}$ | effective concentration reducing by 50% a given parameter |
| EEC | estimated environmental concentration |
| g | gram(s) |
| h | hour(s) |
| ha | hectare(s) |
| kg | kilogram(s) |
| km | kilometre(s) |
| L | litre(s) |
| $LC_{50}$ | lethal concentration to 50% |
| LEL | lowest effect level |
| LERAP | Local Environment Risk Assessment for Pesticides |
| m | metre(s) |
| mg | milligram(s) |
| MRL | maximum residue limit |
| NOEC | no observed effect concentration |
| PMRA | Pest Management Regulatory Agency |
| ppb | parts per billion |
| ppm | parts per million |
| PRVD | Proposed Re-evaluation Decision |
| RED | Reregistration Eligibility Decision |
| REI | restricted-entry interval |
| SCI-GROW | Screening Concentration in Ground Water |
| SERG | Spray Efficacy Research Group |
| TRED | Tolerance Reassessment Eligibility Document |
| USEPA | United States Environmental Protection Agency |

# Appendix I Comments and Responses

## 1.0 Comment on the Date of the Documentation Used in the Assessment

The use of an assessment from 13 years ago (i.e. the 1994 Reregistration Eligibility Decision [RED] document) does not seem appropriate. Using updated available scientific information would be preferable to using the data included in the USEPA RED on hexazinone.

**Response**

The re-evaluation of hexazinone was based on a 1994 RED in addition to a more recent 2002 Tolerance Reassessment Eligibility Document (TRED). Together, these documents cover the main science areas (i.e. human health and the environment) that are necessary for Canadian regulatory decisions, address the main formulation types registered in Canada and are relevant to registered Canadian uses.

## 2.0 Comment on Postapplication Exposure and Risk

An objection was raised to the proposed requirement for a restricted-entry interval (REI) of 48 hours for granular end-use products, based on the fact that the USEPA did not assess occupational postapplication risks to agricultural workers because no dermal endpoint of concern was identified. An REI of 12 hours would be acceptable as it was proposed in PRVD2007-13 for end-use products used as liquids.

**Response**

The USEPA changed the REI from 24 to 48 hours based on the worker protection standard because hexazinone is in Toxicity Category I for primary eye irritation. However, this 48-hour REI is a requirement for all products (i.e. products applied as either a granular or a liquid). The label amendment in Appendix IV of PRVD2007-13 is incorrect to state that an REI of 48 hours is only required for granular products. The 48-hour REI is required for all product formulations with the exception of the use on non-cropland areas (Registration Number 14163) where workers can re-enter the site after 12 hours or when sprays have dried.

The revised label amendments are listed in Appendix II.

## 3.0 Comment on the Groundwater Drinking Water Assessment

It is likely that the blueberry growing season in the United States is longer and that the climate is milder than in some parts of Canada where blueberries are cultivated (e.g. Quebec). Thus, hexazinone may degrade faster in the United States than in Canada. The PMRA should specify whether it took these differences into account in the assessment. Furthermore, the estimated groundwater concentration was compared to a standard level of concern associated with acute exposure and a level of concern associated with chronic exposure, but these values are not mentioned in the PRVD.

**Response**

In the USEPA RED for hexazinone, the estimated environmental concentration (EEC) of 41.8 ppb (total residues) for groundwater is based on a groundwater prospective monitoring study in Merced county, California, where hexazinone was broadcast at a rate of 0.84 kg a.i./ha on an alfalfa crop in an area of sandy soil. This value is of the same order of magnitude as the groundwater concentration estimated from a Tier I model Screening Concentration in Ground Water (SCI-GROW) (i.e. 20.2 ppb), which was based on one application to alfalfa at the maximum application rate of 1.68 kg a.i./ha. The prospective monitoring study was considered to be a conservative estimate of groundwater drinking water exposure by the USEPA because the total residues (41.8 ppb) detected in the study were twice the residue level estimated through the SCI-GROW model (20.2 ppb).

Monitoring data were also available from Maine (where hexazinone was used on blueberries), but the USEPA used these values for comparison purposes only. A maximum concentration of parent hexazinone was detected at 2.15 ppb in 1998 and at 1.97 ppb in 1999, which is similar to the maximum parent concentration of 9.2 ppb observed in the groundwater monitoring study conducted in California.

Drinking water levels of comparison (DWLOCs) were calculated by the USEPA for its Tolerance Reassessment Eligibility Document (TRED). The USEPA concluded that for acute drinking water risk, the EEC in groundwater of 41.8 ppb was below the acute DWLOC for females (13–50 years) of 120 000 ppb. For chronic drinking water risk, the EEC of hexazinone in groundwater of 41.8 ppb was below the chronic DWLOC of 1700 ppb for all population subgroups and below the chronic DWLOC of 425 ppb for the most highly exposed subgroup of children aged 1 to 6. These levels are below the USEPA's level of concern.

Given that the groundwater EEC is well below the USEPA's level of concern for acute and chronic drinking water risk with respect to groundwater and because this is considered to be a conservative estimate, the USEPA's assessment is considered applicable to the Canadian situation, including the blueberry growing regions of Quebec.

The PMRA will review Canada-specific water data to confirm that acceptable levels are not exceeded (see Appendix I, PRVD2007-13). Should the review of additional monitoring data submitted after this decision raise concerns, the PMRA will revisit the decision and consult with provinces and other stakeholders about follow up regulatory action.

## 4.0 Comment on Groundwater Contamination Mitigation

In PRVD2007-13 the PMRA proposed adding a groundwater advisory to the labels of all products as follows.

Hexazinone demonstrates the properties and characteristics associated with chemicals detected in groundwater. The use of this chemical may result in contamination of groundwater particularly in areas where soils are permeable (e.g. sandy soil) and/or the water table is shallow.

This warning is not in itself a measure to reduce the risk of groundwater contamination. The labels of end-use products containing hexazinone do not propose any measure that may reduce the risk of contamination.

**Response**

This statement is advisory in nature. Further mitigation was not required on the label because the risk with respect to drinking water from groundwater sources was not found to be of concern based on the current use pattern and label rates of hexazinone in Canada and on the USEPA assessment.

## 5.0 Comment on the Levels of Concern Used in the Environmental Risk Assessment

The PMRA did not specify the values for the various levels of concern used in the environmental risk assessment.

**Response**

The established levels of concern used in the environmental risk assessment can be found in the USEPA RED for hexazinone. They are as follows.

| Endpoint/Scenario | Risk Quotient | Non-Endangered Species Level of Concern | Endangered Species Levels of Concern |
|---|---|---|---|
| Mammalian acute | $EEC/LC_{50}$ | 0.5 | 0.1 |
| Mammalian chronic | EEC/LEL* | 1.0 | 1.0 |
| Avian acute | $EEC/LC_{50}$ | 0.5 | 0.1 |
| Avian chronic | EEC/LEL | 1.0 | 1.0 |
| Aquatic acute | $EEC/LC_{50}$ | 0.5 | 0.05 |
| Aquatic chronic | EEC/LEL | 1.0 | 1.0 |

* Lowest effect level

## 6.0 Comment on the Requirement for Buffer Zones for the Protection of Aquatic Habitats

The scale proposed for buffer zones should be revised so as not to reflect the potential dilution of a watercourse. The PMRA should take into account a study[5] that shows the presence of hexazinone in five of six rivers sampled in Saguenay-Lac-Saint-Jean, Quebec. The results of this study showed that, in 2007, hexazinone was detected in 10 of 11 samples at levels ranging from 0.01 to 0.028 ppb in the Mistassini River, the largest of the six rivers. In the smallest of the six rivers sampled, concentrations of hexazinone varied between 1.7 and 3.2 ppb during the summer.

In addition, the buffer zone currently specified on the labels of hexazinone is 50 m. In PRVD2007-13, the PMRA proposed buffer zones for the protection of marine habitats ranging from 0 to 2 m based on an USEPA RED dating back 13 years. An explanation is required to justify this important change in buffer zone.

**Response**

The data presented in the Giroux (2008) study[5] indicate that hexazinone concentrations are greater in small rivers (1.7–3.2 ppb) than in large rivers (0.01–0.028 ppb) by approximately 2 orders of magnitude. This reflects potential dilution in watercourses, which is dependent upon water depth.

Buffer zones for the protection of aquatic habitats are determined on the basis of potential concentrations in bodies of water and on the toxicity endpoint of concern. The toxicity data for hexazinone indicate that the endpoints of concern (63 and 6000 ppb for the most sensitive species) are 3 and 5 orders of magnitude greater that the highest hexazinone concentration of 0.028 ppb detected in Mistassini River. Similarly, for the smallest of the six small rivers, the endpoints of concern (63 and 6000 ppb for the most sensitive species) are 1 and 3 orders of magnitude greater than the highest hexazinone concentration of 3.2 ppb (detected during the summer).

It should be noted that, in the PMRA risk assessment and determination of buffer zones, hexazinone concentrations in aquatic systems were estimated to be 100–2900 ppb. These estimated concentrations were based on the scenario of a water body receiving the maximum cumulative application rate of hexazinone. Thus, the PMRA assessment is more conservative (more protective) in this case than using measured environmental concentrations.

The previous buffer zone of 50 m was a default designation that was not based on an environmental risk assessment. The more recent PMRA determination of buffer zones is science-based as it considers both exposure (by using spray drift models) and the toxicity endpoints of concern.

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5 Giroux, I. 2008. *Bilan sur la présence d'hexazinone dans des cours d'eau près de bleuetières du Saguenay Lac Saint-Jean*, Ministère du Développement durable de l'Environnement et des Parcs.

## 7.0 Comment on the Toxicity Endpoint Used to Calculate Aquatic Buffer Zones

As stated in Appendix V of PRVD2007-13, the most sensitive toxicity endpoint reported in the USEPA's 1994 RED and used to calculate aquatic buffer zones was an $LC_{50}$ of 2.1 mg/L based on the acute toxicity of hexazinone to *Anabaena flos-aquae*. However, the concentration of 0.03 mg/L (Abou-Waly 1991)[6] is more sensitive and should be used as the toxicity endpoint to calculate aquatic buffer zones for hexazinone.

**Response**

In Appendix V of PRVD2007-13, the 1/10 of the $LC_{50}$ value (i.e. 0.21 mg/L) is a typographical error. The value used in the buffer zone model to calculate aquatic buffer zones was 1/10 of the $LC_{50}$ of 0.21 mg/L (i.e. 0.021 mg/L).

However, the PMRA has reviewed the data in Abou-Waly 1991 and determined that *Selenastrum capricornutum*, with an $EC_{50}$ of 0.126 mg/L, is a more sensitive endpoint and the aquatic buffer zones have been recalculated to reflect this. In addition, the PMRA's current methods use half of the $EC_{50}$ (rather than 1/10 of the $EC_{50}$); therefore half the $EC_{50}$ of 0.126 mg/L (i.e. 0.063 mg/L) was used to re-calculate the aquatic buffer zones. See Appendix II for the revised buffer zones and Appendix III for the revised buffer zone inputs.

## 8.0 Comment on Wind speed in Aerial Application Scenarios

Aerial buffer zones were calculated in PRVD2007-13 based on a 16 km/h wind speed and "bare earth" assumption. Currently, aerial forestry application is conducted in winds less than 10 km/h. Therefore, the aerial buffer zones in PRVD2007-13 are not reflective of what is currently taking place.

**Response**

According to the Velpar L Herbicide (Registration Number 18197) and Velpar DF Herbicide (Registration Number 25225) labels, the aerial application of hexazinone to woodland management areas and Christmas tree plantations is not permitted at wind speeds greater than 15 km/h. The PMRA default wind speed is 16 km/h for the AGDISP model simulation and is, therefore, not a significant departure from the wind speed listed on the label. In addition, the PMRA considers a spray drift interception of 50% by the forest canopy when modelling drift using AGDISP and, as such, the modelling scenario is not considered as a "bare-earth" application.

6 Abou-Waly H. et al. 1991. Growth Response of Freshwater Algae, *Anabaena flos-aquae* and *Selenastrum capricornutum* to Atrazine and Hexazinone Herbicides. *Bulletin of Environmental Contamination and Toxicology* 46: 223–229.

## 9.0 Comment on the Potential Interception of Spray Drift in Aerial Applications

The Canadian Forest Service is currently carrying out a number of research projects[7] pertaining to operational herbicide spraying in forestry. The result of one of the projects[8] demonstrates significant interception of potentially drifting spray clouds by standing timber required by law around lakes and streams and by natural riparian vegetation that occur typically around water bodies.

**Response**

As two of the above-mentioned projects regarding advances in application technology and post-treatment assessment are apparently ongoing, these data will be most beneficial to the PMRA when they become available. The PMRA is currently examining drift reduction technologies as a means of providing additional tools for applicators.

The PMRA will need to quantify the interception of spray drift by surrounding riparian vegetation to substantiate aerial modelling that would result in reduced buffer zones for the protection of aquatic habitats. This quantification of spray interception could be applied generically provided that there are data to account for spray quality (as spray interception may differ depending on the droplet size spectrum) as well as the porosity of the vegetative barrier (which may differ substantially between types of riparian zones). Currently, the PMRA has not determined an appropriate spray interception value attributed to riparian zones as these data are largely not available.

## 10.0 Comment on Recent Advances in Forestry Aerial Application Technologies

The Spray Efficacy Research Group (SERG) International could provide valuable input to the PMRA's deliberations. SERG International is an association of forest managers, scientists and industry representatives with a primary goal of improving pesticide application technology within the context of integrated forest pest management. This association includes experts in aerial forest pesticide application and environmental impacts that could work with the PMRA to develop realistic and practical buffer zones for hexazinone applications in forestry.

**Response**

The PMRA routinely attends the annual SERG International meetings as part of its role in maintaining an open dialogue with forestry applicators and industry representatives. Information gathered from these meetings has been instrumental in the PMRA's approach for modeling aerial applications for a forestry scenario. It should be noted that the PMRA has not received any

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7 A summary of the research projects 160-201 and 160-401 was provided to the PMRA with the comment. Information on the Canadian Forest Service research projects is available at www.forestresearch.ca/

8 Thompson, D.G. et al. 2004. Chemical and Bio-monitoring to assess potential acute effects of VISION herbicide on native amphibian larvae in forest wetlands. *Environmental Toxicology and Chemistry* 23: 843–849.

substantive data from SERG International on environmental impacts that would refute the PMRA's buffer zones for forestry applications of hexazinone.

### 11.0 Comment on the Size of Aerial Buffer Zones

The forest industry, scientific research community and government agencies have a working history with the current standards (i.e. current buffer zones and new aircraft navigational systems). Furthermore, the province of Ontario has used buffer zones (60-120 m) around water bodies since 1992, which were developed jointly between the Ministry of Natural Resources and the Ontario Ministry of the Environment.

Application technology is constantly improving with electronic guidance and improved nozzle technologies that greatly improve accuracy and reduce the production of driftable droplets. This could be acknowledged by allowing operators flexibility in adapting aerial application buffer zones based on spray characteristics, wind speed and habitat sensitivity and not by prescribing minimum buffer zones as in Appendix IV of PRVD2007-13.

In addition, what is the rationale for different size buffer zones between rotary and fixed wing aircraft?

**Response**

The latest PMRA update of buffer zones for hexazinone (March 2008) was based on a spray droplet size of ASAE coarse (see the table of buffer zone sizes given in Appendix II). For aerial application on woodlands (which includes conifer release), the updated buffer zones of 35 and 50 m are in close agreement with the product label statement "Do not apply within 50 meters of water bodies to prevent possible injury to aquatic plants" and with the Ontario buffer zone guidelinc (60–120 m).

The PMRA is developing an approach that considers the latest nozzle and spraying technologies aimed at reducing spray drift. For example, the Local Environment Risk Assessment for Pesticides (LERAP) system of ranking the drift reduction potential of spray nozzles implemented in the United Kingdom will be considered as a viable approach for inclusion in the PMRA's Buffer Zone Strategy. The proposed strategy will provide flexibility to the applicator in the form of buffer zone reduction multipliers that are based on operational conditions (e.g. wind speed, spray quality and boom height).

With regard to different buffer zones between rotary-wing and fixed-wing aircraft, according to the simulations of the AGricultural DISPersal (AGDISP) model, different spray drift patterns are produced as a result of aircraft-specific wingtip vortices that are generated during flight. Thus, the extent of spray drift deposit is a function of aircraft type.

## 12.0 Comment on Definitions of Habitats

Further explanation is required to define what is meant by "terrestrial habitat" and "estuarine/marine habitat" as it pertains to a forested environment. An explanation is needed to define what is meant by "buffer zones for protection of terrestrial habitats are not required for spraying of rights-of-way".

**Response**

For herbicide applications in forestry for conifer release, adjacent forested areas (which may be designated as "terrestrial habitats") are also intended for herbicide treatment and harvest and, thus, are not considered to be non-target terrestrial areas. Buffer zones are, therefore, not required for this herbicide treatment scenario.

"Estuarine/marine habitats" may consist of semi-enclosed bodies of water or expansive wetland areas along the coastline. These habitats are often adjacent to forested areas intended for pesticide treatment.

As rights-of-way are relatively narrow tracks of land that are cleared of vegetation and considered to be "habitat" for purposes of accessibility, it would be counterproductive to impose buffer zones to protect this type of terrestrial habitat as the purpose here is to remove or control vegetation in one area of that habitat.

## 13.0 Comment on the Label Statement Regarding Spray Droplet Size

The proposed label wording on the size of spray droplets is not precise enough to be easily applicable in the field.

> DO NOT apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification.

Rather than the applicator having to refer to another entity (ASAE) or documentation to comply with the recommendation of the label, the PMRA should include all of the information with regard to the droplet size on the label because this may facilitate greater compliance.

**Response**

The droplet size categories are indicated in the manuals that come with the various spray nozzles; it should not be problematic for applicators to determine the appropriate spray volumes and pressures required to achieve a particular droplet size spectrum. In the absence of manuals, this information may be accessible online; thus, applicators should determine the spray parameters required for achieving the prescribed droplet classification before using the product.

## 14.0 Comment on the Exemption of Terrestrial Buffer Zones for Rights-of-way

A request was made to expand the exemption that terrestrial buffer zones are not required for rights-of-way to include industrial sites (i.e. petroleum tank farms, industrial plant sites, lumberyards, military bases).

The PMRA was also asked to clarify that buffer zones for site preparation or conifer release for forestry uses are no longer required. Given that aerial applications of hexazinone are solely for site preparation in woodland management areas, buffer zones for woodland management and reforestation should no longer be required.

**Response**

The latest PMRA update of buffer zones for hexazinone (March 2008) was based on a spray droplet size of ASAE coarse (see the table of buffer zone sizes given in Appendix II). For application to non-cropland areas (which include industrial areas), the updated buffer zone for protecting terrestrial habitats is 15 m. As indicated in a footnote to the buffer zone table, the buffer zone for field sprayer applications can be reduced by 70% using spray booms fitted with a full screen (shroud or curtain) or by 30% using cone-shaped shields fitted to individual nozzles. Thus, the PMRA will not exempt the observance of terrestrial-habitat buffer zones for industrial areas as drift reduction equipment are available. The PMRA will, however, exempt the terrestrial habitat buffer zones for herbicide treatment on military bases as there are safety issues regarding unexploded ordnances in these areas (i.e. firing ranges).

As hexazinone treatment of woodland management areas is solely for site preparation (reforestation), buffer zones for the protection of terrestrial habitats are not required for the application of hexazinone for woodland management (see the table of buffer zone sizes given in Appendix II).

## 15.0 Comment on the Environmental Hazards Statements

An objection was raised to the proposed groundwater advisory label statement based on the low dietary risk associated with hexazinone (i.e. PRVD2007-13 states that Tier I modeling predicted EECs were below the DWLOC). Based on the low dietary risk, the statement that hexazinone has the potential to *contaminate* drinking water was considered in appropriate.

**Response**

The statement proposed in PRVD2007-13 with respect to the protection of groundwater is not required based on the dietary risk of hexazinone. The expected drinking water concentration based on a groundwater prospective monitoring study was found to be lower than the drinking water levels of concern (DWLOCs) for the acute and chronic exposure scenarios, and no further mitigation measures were required. However, the PMRA requires general guidance for the protection of groundwater on all product labels when a product is determined to be susceptible to

leaching. As a result, the following statement (updated to reflect current standards) will continue to be required in the ENVIRONMENTAL HAZARDS section of the label.

> The use of this chemical may result in contamination of groundwater particularly in areas where soils are permeable (e.g. sandy soil) and/or the depth to the water table is shallow.

The revised label amendments are listed in Appendix II.

## 16.0 Comment on the Proposed Environmental Hazards Statements

Hexazinone is deemed most effective when rain occurs shortly after applying the product; therefore, the user will tend to apply the product shortly before a rain. However, the PMRA recommends to "Avoid application of this product when heavy rain is forecast". The intensity of the rain is rather subjective. The PMRA should specify what is meant by a heavy rain.

**Response**

The statement "Avoid application of this product when heavy rain is forecast" is required as a standard label statement regarding runoff on all product labels. Regardless of the attributes of the active ingredient, runoff due to heavy rain can occur with compounds that are soluble in water (runoff with flow of water) or adsorbed into soil (soil-particle movement in runoff water). Both types of compounds can enter aquatic systems through runoff and pose a risk to either free-swimming or sediment-dwelling organisms, respectively. It is assumed that judgment is used by the applicator to determine what is considered a heavy rain and to avoid losing product due to runoff.

## 17.0 Comment on Water Monitoring Data and Drinking Water Quality Standards

In Appendix I of PRVD2007-13, the registrant is asked to provide data to confirm that acceptable levels of hexazinone and its metabolites in groundwater and surface water are not exceeded. The acceptable levels are not specified in PRVD2007-13.

PRVD2007-13 states that there is no water quality guideline for hexazinone in Canada. How will the PMRA determine the acceptability of the monitoring data requested from the registrants if there is no water quality guideline?

**Response**

As a result of the potential for hexazinone to reach water sources, according to the USEPA's review and previous Canadian reports, the PMRA is requiring that registrants provide the PMRA with data to confirm that acceptable levels of hexazinone and its metabolites in groundwater and surface water are not exceeded in Canadian waters. The reference levels (i.e. acceptable levels) that will be used for that comparison are the most sensitive acute and chronic DWLOCs (i.e. acute: 120 000 ppb; chronic: 425 ppb) calculated by the USEPA for its TRED (see the table below).

| Population Subgroup | Acute DWLOC (ppb) | Chronic DWLOC (ppb) |
|---|---|---|
| General American population | — | 1 700 |
| Females (13–50 years) | 120 000 | 1 500 |
| All infants | — | 460 |
| Chilren (1–6 years) | — | 425 |

The PMRA has already considered the weight of evidence with regard to the acceptability of hexazinone for use in Canada; therefore, these data are requested to confirm that decision. Should the review of additional monitoring data submitted after this decision raise concerns, the PMRA will revisit the decision and consult with provinces and other stakeholders about follow up regulatory action.

### 18.0 Comment on the Registration Currently In Place to Protect Wildlife and Sensitive Habitats

There are already laws in place that protect biodiversity in forests (the *Ontario Crown Forest Sustainability Act*), water (the *Ontario Water Resources Act*) and fish habitats (the federal *Fisheries Act*).

**Response**

Although laws exist to protect biodiversity in forests, water and fish habitats, the prescribed provincial buffer zones protecting these habitats are generic and are not based on the environmental risk determined for a particular pesticide. For example, the Ontario Ministry of Natural Resources' buffer zones of either 60 m (for "significant areas") or 120 m (for "sensitive areas") are applicable for all herbicide products. By contrast, the PMRA's buffer zones are specific to the herbicide and to the operational conditions (e.g. wind speed, boom height, spray quality) under which the herbicide is applied.

# Appendix II Label Amendments for Products Containing Hexazinone

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on the labels of currently registered products should not be removed unless it contradicts the label statements below.

The labels of all end-use products in Canada must be amended to include the following statements to further protect workers and the environment.

I) The following statements must be included in the **PRECAUTIONS** section.

> Wear a long-sleeved shirt, long pants and shoes plus socks during application. In addition, wear chemical-resistant gloves and goggles or a face shield during mixing/loading, clean-up or repair activities and when using handheld application equipment.

For all end-use products for use on alfalfa, blueberries, Christmas tree plantations, and woodland management areas, the following statement must be included.

> Do not enter or allow entry into treated area until 48 hours after application.

In addition, for the end-use product with Registration Number 14163 for use on non-cropland areas (railroad, highway, utility and pipeline rights-of-way, petroleum tank farms, storage areas, industrial plant sites and other similar sites), the following statement must be included.

> Do not enter or allow worker entry into treated areas until 12 hours after application or until sprays have dried.

II) The following statements must be included in the **DIRECTIONS FOR USE** section on the labels of all formulations (except granular).

> Field sprayer application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) coarse classification. Boom height must be 60 cm or less above the crop or ground.
>
> Aerial application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply when wind speed is greater than 16 km/h at the site of application. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) coarse classification. To reduce drift

caused by turbulent wingtip vortices, the nozzle distribution along the spray boom length **MUST NOT** exceed 65% of the wing- or rotorspan.

**Buffer zones:**

Use of the following spray methods or equipment **DO NOT** require a buffer zone: handheld or backpack sprayer and spot treatment.

For application to rights-of-way, buffer zones for the protection of sensitive terrestrial habitats are not required; however, the best available application strategies that minimize off-site drift, including meteorological conditions (e.g. wind direction, low wind speed) and spray equipment (e.g. coarse droplet sizes, minimizing height above canopy), should be used. Applicators must, however, observe the specified buffer zones for protection of sensitive aquatic habitats.

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas and shrublands) and sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands).

| Method of Application | Crop | | Buffer Zones (metres) Required for the Protection of: | | |
|---|---|---|---|---|---|
| | | | Freshwater Habitat of Depths: | | Terrestrial Habitat |
| | | | Less than 1 m | Greater than 1 m | |
| Field sprayer* | Established seed alfalfa, blueberries, established conifers (conifer release) | | 1 | 1 | 5 |
| | Woodland management (less than 500 ha) | | 1 | 1 | NR |
| | Non-cropland | | 1 | 1 | 15** |
| Aerial | Woodland management (less than 500 ha) | Fixed wing | 50 | 4 | NR |
| | | Rotary wing | 35 | 1 | NR |

* For field sprayer application, buffer zones can be reduced with the use of drift reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy, the labelled buffer zone can be reduced by 30%.

** Buffer zones for the protection of terrestrial habitats are not required for use on rights-of-way including railroad ballast, rail and hydro rights-of-way, utility easements and roads.

NR: Buffer zones for the protection of terrestrial habitats are not required for use in forestry and woodlot management.

III) The following statements must be included in the **ENVIRONMENTAL HAZARDS** section.

**TOXIC** to aquatic organisms and non-target terrestrial plants. Observe buffer zones specified under **DIRECTIONS FOR USE**.

The use of this chemical may result in contamination of groundwater particularly in areas where soils are permeable (e.g. sandy soil) and/or the depth to the water table is shallow.

To reduce runoff from treated areas into aquatic habitats, avoid application to areas with a moderate to steep slope, compacted soil, or clay.

Avoid application when heavy rain is forecast.

Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body.

# Appendix III Revised Inputs to Buffer Zone Models

## Ground Use Data (from Canadian labels)

| Crop | Formulation Type | Method of Application | Number of Applications | Maximum Application Rate (g a.i./ha) |
|---|---|---|---|---|
| Woodland management | End-use product used as liquid | Field sprayer (ASAE coarse) | 1 | 4320 |
| Christmas tree plantations | End-use product used as liquid | Field sprayer (ASAE coarse) | 1 | 1992 |
| Established seed alfalfa | End-use product used as liquid | Field sprayer (ASAE coarse) | 1 | 1010 |
| Blueberries | End-use product used as liquid | Field sprayer (ASAE coarse) | 1 | 2030 |
| Non-cropland | End-use product used as liquid | Field sprayer (ASAE coarse) | 1 | 8010 |

## Model Input Data for Aquatic Buffer Zones (from 1994 RED)

| | | |
|---|---|---|
| Half-life for aquatic buffer zones | Assumed stable | |
| Most sensitive amphibian species | Fathead minnow (surrogate) | NOEC = 17 mg a.i./L |
| Most sensitive freshwater species | *Selenastrum capricornutum*[9] | ½ $EC_{50}$ = 0.063 mg/L |
| Most sensitive estuarine/marine species | *Skeletonema costatum* | ½ $LC_{50}$ = 6 mg/L |

## Model Input Data for Terrestrial Buffer Zones (from 1994 RED)

| | | |
|---|---|---|
| Half life for terrestrial buffer zones | assumed stable | |
| Most sensitive terrestrial plant species $EC_{25}$ for vegetative vigour | tomato (seedling emergence) | $EC_{25}$ = 7.19 g a.i./ha |

## Aerial Use Data (from Canadian Labels)

| Crop | Formulation Type | Registration Number | Number of Applications | Rate of Application (g a.i./h) |
|---|---|---|---|---|
| Woodland management | water dispersible granule | 18197 | 1 | 4320 |
| Woodland management | water dispersible solution | 25225 | 1 | 4320 |

[9] from Abou-Waly H. et al. 1991

## Product Information for Aerial Use

| Parameter | Value |
|---|---|
| Registration Number 18197 | |
| Aircraft type | Fixed and/or rotary |
| ASAE spray quality | Coarse |
| Carrier | Water |
| Product guarantee (g a.i./L) | 240 |
| Specific gravity of end-use product (g/L) | 970 |
| Minimum spray volume (L/ha) | 35 |
| Water content of product (%) | 30 |
| Wind speed (km/h) | 16 |
| Temperature (°C) | 25 |
| Relative humidity (%) | 50 |
| Registration Number 25225 | |
| Aircraft type | Fixed and/or rotary |
| ASAE spray quality | Coarse |
| Carrier | Water |
| Product guarantee (g a.i./L) | 750 |
| Specific gravity of end-use product (g/L) | 1000 |
| Minimum spray volume (L/ha) | 35 |
| Water content of product (%) | 0 |
| Wind speed (km/h) | 16 |
| Temperature (°C) | 25 |
| Relative humidity (%) | 50 |

# References

## Studies considered in the Chemistry Assessment

### LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT

| PMRA Document Number | Reference |
|---|---|
| 1465265 | 1989, Technical Hexazinone Analysis and Certification of Product Ingredients and Confidential Attachment Supplement No. 1, A3674.F, DACO: 2.13.3 |
| 1465242 | Technical Chemistry file - Hexazinone Technical and some published articles. Determination of Hexazinone and Metabolite Residues Using Nitrogen-Selective Gas Chromatography (Agricultural and Food Chemistry, 1981, 29 165). Tolerance and Residues of Hexazinone, DACO 2.11 |

## Studies considered for the Response to Comments

### ADDITIONAL INFORMATION CONSIDERED

### Published Information

Abou-Waly H. *et al.* 1991. Growth Response of Freshwater Algae, *Anabaena flos-aquae* and *Selenastrum capricornutum* to Atrazine and Hexazinone Herbicides. Bull. Environ. Contam. Toxicol. 46: 223-229.